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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,372	01/19/2001	Harold Richardson Crews	708-A01-007	8926

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	5

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/766,372	CREWS ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4-17 and 21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-3 and 8-10 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that claims 10-12 were improperly grouped in groups III and IV and should instead be grouped in group I. This is not found persuasive because while claims 10-12 recite a lytic reagent composition, they do not share any of the limitations found in the stromatolysing reagent of group I. Furthermore, while examiner does recognize the fact that groups III and IV are each comprised of two distinct inventions, a kit and a composition, it was felt that the search required for the kits of groups III and IV would encompass the compositions recited in claims 10-12 and therefore would not constitute an undue burden for the examiner. However, should applicant strongly feel that the inventions be prosecuted separately, applicant may wish to file separate divisional applications for the kits and compositions of groups III and IV.

2. The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: in claims 1 and 18, the limitation "trialkylammonium halide salt where the alkyl group is selected from the class consisting of alkyl radicals having 8-12 carbons having surface active properties" is not found in the specification. The specification does disclose a

reagent comprising a "trialkylmethylammonium" halide salt, however, which is a tetraalkylammonium halide salt.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3, 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites the limitation "having surface active properties". It is unclear whether this limitation is referring to the alkyl radicals, the 8-12 carbons, the trialkylammonium halide salt, or the aqueous solution. This is also applicable to the same limitation recited in claim 18.
Claim 1 recites the Markush group "dodecyl, tetradecyl and hexadecyl". It is unclear if applicant means a tetraalkylammonium halide salt with a dodecyl, tetradecyl, or hexadecyl group or if applicant means a tetraalkylammonium halide salt with a dodecyl or tetradecyl and hexadecyl group. The same ambiguity is found in claim 18 regarding the Markush group consisting of "methyl, dodecyl, tetradecyl, hexadecyl, 2-hydroxyhexadecyl and 2-hydroxyehtyl".

7. Claim 1 recites the limitation "the alkyl group" in lines 6-7 of the claim. There is insufficient antecedent basis for this limitation in the claim. Although applicant discloses in the specification that only one of the alkyl groups is actually a dodecyl, tetradecyl, or hexadecyl group, from the claim, it could be interpreted that each of the alkyl groups is chosen from the

group consisting of "dodecyl, tetradecyl, and hexadecyl" groups, rendering the claim unclear and ambiguous.

8. Claim 1 recites the limitation "the alkyl group" in line 8 of the claim. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether only one of the alkyl groups has 8-12 carbons, or if all of them do. It is also unclear if they alkyl groups are all the same, or if they are different alkyl groups. This is also applicable to the same limitation in line 8 of the same claim and in line 9 of claim 18.

9. In claims 1 and 18, applicant recites the limitation "surface active properties". It is unclear what is meant by the term "surface active properties", and applicant fails to clearly define the term in the specification, rendering the claim unclear and ambiguous.

10. The term "sufficient amounts" in claims 1 and 18 is a relative term which renders the claims indefinite. The term "sufficient amounts" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear the amount of salts that would be necessary to constitute a "sufficient amount for positioning the leukocyte populations relative to one another, and it is unclear whether some of the salts are even necessary for positioning the leukocyte populations relative to one another.

11. Claims 1 and 18 provides for the use of a stromatolysing reagent in the determination of at least two leukocyte populations in blood, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps

delimiting how this use is actually practiced. The claims are therefore treated solely as product claims, and any use of the products is not taken into consideration.

12. The remainder of the claims are deemed indefinite due to their dependence on indefinite claims.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

14. Claims 1 and 18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

16. Claims 1-3, 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Crews et al [US 6,632,676 B1].

17. Crews et al teach a stromatolysing reagent comprising an aqueous solution of a tetraalkylammonium halide salt with an alkyl group selected from the class consisting of dodecyl, tetradecyl, and hexadecyl (column 8,line 1-6) and a trialkylammonium halide salt with an alkyl group having 8-12 carbons and having surface active properties (column 8, line 9-19).

18. With respect to claims 2-3, Crews et al further teach a stromatolysing reagent comprising a 2-hydroxycetyl-2-hydroxyethyldimethylammonium halide salt (column 8, line 23-26).

19. With respect to claim 18, Crews et al teach a stromatolysing reagent comprising an aqueous solution of a tetraalkylammonium halide salt with an alkyl group selected from the class consisting of dodecyl, tetradecyl, hexadecyl, 2-hydroxyhexadecyl, and 2-hydroxyethyl (column 8,line 1-6) and a trialkylammonium halide salt with an alkyl group having 8-12 carbons and having surface active properties (column 8, line 9-19).

20. With respect to claim 19-20, Crews et al teach a reagent comprising methyl paraben (column 9, lines 45-50).

21. Claims 1-3, 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Golinski et al [US 6,528,045].

22. With respect to claims 1 and 18, Golinski et al teach a reagent comprising cationic surfactants such as quaternary ammonium compounds with one or two alkyl or alkenyl groups with 10 to 22 carbon atoms in the molecule, in an amount from 0.1 to 5% (column 4, lines 15-

22). This would include tetraalkyl ammonium halides with dodecyl, tetradecyl, or hexadecyl compounds as well as trialkylammonium halides with an alkyl group 8-12 carbons long having surface active properties (since surfactants are surface active by definition).

23. With respect to claims 2-3, Golinski et al further teach a reagent comprising hydroxyethyl hydroxycetyl dimonium chloride (or hydroxycetyl hydroxyethyl dimethylammonium chloride) (column 4, lines 27).

24. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ledis et al [US 4,286,963].

25. Ledis et al teach a reagent comprising an aqueous solution of a tetraalkylammonium halide salt with an alkyl group selected from the class consisting of dodecyl, tetradecyl, and hexadecyl and a trialkylammonium halide salt with an alkyl group having 8-12 carbons and having surface active properties (column 3, lines 25-60). For example, Ledis et al teach a reagent comprising an alkyl radical having 12 carbon atoms (which can be considered a tetraalkylammonium halide salt with an dodecyl group as well as a trialkylammonium halide salt with an alkyl group having 8-12 carbons). Ledis further teach that the quaternary ammonium salt has surface active properties, and is present in 200-500mg/L for positioning leukocyte populations (column 3, line 24-26, claim 9).

26. Claims 1 and 18 are rejected under 35 U.S.C. 103(a) as being anticipated by Kashiwabara et al [US 6,200,588 B1].

27. Kashiwabara et al teach a reagent comprising an aqueous solution of a tetraalkylammonium halide salt with an alkyl group selected from the class consisting of

dodecyl, tetradecyl, and hexadecyl and a trialkylammonium halide salt with an alkyl group having 8-12 carbons and having surface active properties (column 7, comparative example 2). For example, Kashiwabara et al teach a reagent comprising tridodecylmethylammonium chloride (which can be considered a tetraalkylammonium halide salt with a dodecyl group as well as a trialkylammonium halide salt with an alkyl group having 8-12 carbons), as well as a reagent comprising dimethyldidodeceylammonium chloride (trialkylammonium halide salt with an alkyl group having 8-12 carbons) and dimethylditetradecyl ammonium chloride (tetraalkylammonium halide salt with a tetradecyl group). Kashiwabara further specifies that over 15% of the reagent is comprised of salts (column 7, lines 5-9).

Claim Rejections - 35 USC § 103

28. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

29. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golinski et al [US 6,528,045 B1] in view of Ledis et al [US 4,751,179].

30. Golinski et al teach the use of a reagent comprising a tetralkylammonium halide salt and a trialkylammonium halide salt. Golinski et al does not teach a reagent comprising methyl paraben. Ledis et al, however, do teach the use of methyl paraben as a means to inhibit the growth of microorganisms (column 6, lines 3-8). Therefore, it would be obvious to use methyl

paraben, as taught by Ledis et al, in the reagent of Golinski et al, in order to inhibit the growth of microorganisms.

31. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ledis et al [US 4,286,963] in view of Ledis et al [US 4,751,179].

32. Ledis et al teach the use of a reagent comprising a tetralkylammonium halide salt and a trialkylammonium halide salt. Ledis et al does not teach a reagent comprising methyl paraben. Ledis et al, however, do teach the use of methyl paraben as a means to inhibit the growth of microorganisms (column 6, lines 3-8). Therefore, it would be obvious to use methyl paraben, as taught by Ledis et al, in the reagent of Ledis et al, in order to inhibit the growth of microorganisms.

33. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kashiwabara et al [US 6,200,588 B1] in view of Ledis et al [US 4,751,179].

34. Kashiwabara et al teach the use of a reagent comprising a tetralkylammonium halide salt and a trialkylammonium halide salt. Kashiwabara et al does not teach a reagent comprising methyl paraben. Ledis et al, however, do teach the use of methyl paraben as a means to inhibit the growth of microorganisms (column 6, lines 3-8). Therefore, it would be obvious to use methyl paraben, as taught by Ledis et al, in the reagent of Kashiwabara et al, in order to inhibit the growth of microorganisms.

Conclusion

35. No claims are allowed.

36. The following references are also cited as art of interest: Rich [US 5,145,607], Bartels et al [US 6,485,528 B1], Ichikawa et al [US 6,265,479 B1], Kim et al [US 4303,408], and Bedwell et al [US 5,756,592]

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (703) 305-4508. The examiner can normally be reached on 8:30-5:00.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

39. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

NY

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
11/23/03